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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,848	06/18/2001	Leona E. Ling	CIBT-P01-119	9957

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EXAMINER
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FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/883,848

Applicant(s)

LING ET AL.

Examiner

Brandon J. Fetterolf, PhD

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,25-27 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 25-27 and 35-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Ling et al.

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/19/2005 has been entered.

Claims 1-2, 25-27 and 35-38 are currently pending and under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action of 6/04/2002.**

The Declaration filed under 37 CFR 1.131 by Leona Ling is acknowledged and has been carefully considered.

The declaration by Leona Ling sets forth the conception and articulation of specific experiments designed to confirm the effects of hedgehog signaling on angiogenesis, wherein it was realized that exemplary agents including hedgehog protein, lipophilic modified hedgehog proteins, as well as other agonist of hedgehog signaling could be used to activate hedgehog signaling, thereby promoting angiogenesis. Specifically, the declaration (Exhibit 2) depicts the results of an exemplary experiment showing the reduction to practice of promoting angiogenesis using a hedgehog agonist, wherein the hedgehog agonist appears to be sonic hedgehog protein. Thus, while the declaration sets forth the conception of a genus of agonist and the reduction to practice a specific species, i.e. a polypeptide, the declaration is silent on the specific chemical structure any of the other hedgehog agonists, specifically the small organic molecules as described in claim 27. For these reasons, the declaration filed by Leona Ling is not persuasive and has not overcome the rejection under 35 USC 102 (e).

**Rejections Maintained:**

Claims 1-2, 25-27 and 35-38 **remain** rejected under 35 USC 102(e), as being anticipated by Porter et al. (U.S. Patent No. 6,613,798, 03/30/2000) for reasons of record in the Office Actions mailed on 07/15/2004 (page 4) and 10/19/2004 (page 2) and for the reasons set forth below.

Porter et al teaches methods of administering the patentably disclosed agonistic of interest, Exhibit 1 (Agonist D in Patent, Figure 32A-1) to animals for the purpose of activating the hedgehog pathway (column 18, lines 40+). For example, the patent teaches that the hedgehog agonist can be administering for the treatment or prevention of a variety of damaged epithelial and mucosal tissues, such as to control wound healing (column 20, lines 31+). Porter et al. further disclose (column 18, lines 40-43) that small organic agonist can modulate the signal transduction pathways regulated by hedgehog, patched (ptc), gli and/or smoothened. Thus, while porter et al. does not teach that the administration of the agonist would promote angiogenesis, the claimed functional limitation is an inherent property of the referenced method because the specification teaches (page 2, lines 10-16) that "Angiogenesis, the process of sprouting new blood vessels from existing vasculature, ... *is* physiologically important in vascular growth in adult tissues and these processes of vascular growth are required for beneficial processes such as tissue repair, wound healing, ect..." Thus, it does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). Furthermore, since the product of the prior art appears to be identical to that required by the claims, the methods will inherently lead to the promotion of angiogenesis. Thus, since the product of the prior art has the same chemical structure as that described in the specification, it can be assumed that the product will inherently perform the claimed process. (See MPEP 2112.02).

Therefore, NO claim is allowed

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD

Examiner

Art Unit 1642

BF

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER  
8/24/05